PHARMACY OPERATIONS AND DRUG CONTROL

COMDTINST 6000.10

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U.S. Department of Homeland Security

United States Coast Guard

Commandant
United States Coast Guard

US Coast Guard Stop 7907 2703
Martin Luther King Jr Ave
Washington, DC 20593-7907
Staff Symbol: CG-11
Phone: (202) 475-5130

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COMMANDANT INSTRUCTION 6000.10

Subj: PHARMACY OPERATIONS AND DRUG CONTROL

Ref: (a) Coast Guard Medical Manual, COMDTINST 6000.1 (series)
(b) United States Code, Title 21
(c) United States Code, Title 42
(d) Drug Enforcement Agency (DEA), Pharmacist Manual (updated 2020)
(e) Combat Methamphetamine Epidemic Act of 2005
(f) United States Consumer Safety Commission: Poison Prevention Packaging Act of 1970: A Guide for Healthcare Professionals, October 14, 2008
(g) United States Pharmacopoeia, Chapter 795: Pharmaceutical Compounding – Nonsterile Preparations, March 30, 2018
(h) United States Pharmacopoeia Chapter 800: Hazardous Drugs – Handling in Healthcare Settings, July 1, 2018
(i) Hazardous Waste Management Policy, COMDTINST 16478.1 (series)
(j) Physical Security and Force Protection Program, COMDTINST M5330.1 (series)
(k) Financial Resource Management Manual (FRMM), COMDTINST M7100.3 (series)
(l) Standards of Ethical Conduct, COMDTINST M5370.8 (series)
(m) USCG Countering WMD Capabilities Manual (CWMD Manual), COMDTINST 3400.51 (series)
(n) Telehealth, COMDTINST 6300.3 (series)
(o) Use of Imaging and Recording Devices in USCG HealthCare Facilities, COMDTINST 6010.6A
(p) Military Treatment Facility Pharmacy Operations, DHA-PI 6025.31
(q) Military Health System Prescription Drug Monitoring Program DHA-PI 6010-02
(r) Military Health System Drug Take Back (DTB) Program, DHA-PI 6025.25
(s) Clinical Quality Management, DHA-PM 6025.13
(t) Influenza Vaccination Program DHA-PI 6025-34
(u) United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series)
(v) HSWLSCTD 2019-020 Regional Pharmacy Executive (RPE) Area of Responsibility Duty Program
(w) HSWLSCTD 2018- 04 Pharmacy Technician Qualification Guide

1. PURPOSE. This Instruction provides Coast Guard (CG) Pharmacy Operations Policy, based on authorities provided in Reference (a), and in accordance with (IAW) guidance provided by References (b) through (u). It establishes policy to implement and standardize pharmacy operations throughout the CG while maintaining medication management best practices IAW applicable laws and regulations.

2. ACTION. All Coast Guard unit commanders, commanding officers, officers-in-charge, deputy/assistant commandants, chiefs of headquarters directorates must comply with the policies contained herein.

3. AUTHORIZED RELEASE. Internet release is authorized.

4. DIRECTIVES AFFECTED. This is a new Commandant Instruction; the contents replace Chapter 10 of Reference (a) which is consolidated and updated into this Instruction.

5. DISCUSSON. This Instruction removes procedures from CG policy for all pharmacy operations and drug control matters. All pharmacy operations and drug control procedures can be found in Health, Safety, Work-Life Service Center (HSWL SC) technical directives https://cg.portal.uscg.mil/units/hswlsc/SitePages/Unit%20Directives.aspx .

6. DISCLAIMER. This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is intended to provide administrative guidance for Coast Guard personnel and is not intended nor does it impose legally-binding requirements on any party outside the Coast Guard.

7. MAJOR CHANGES. This is the first stand-alone pharmacy operations Instruction for the CG Health Program with significant updates to previous pharmacy policy found in Reference (a).

8. SCOPE AND AUTHORITIES. Readers should become familiar with the directives, publications and references noted throughout this Instruction. This Instruction applies to all CG pharmacies, clinics and sick bays (ashore and afloat) that store and dispense medications.

9. ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS. The Office of Environmental Management, Commandant (CG-47) reviewed this Commandant Instruction and the general policies contained within, and determined that this policy falls under the Department of Homeland Security (DHS) categorical exclusion A3. This Commandant Instruction will not result in any substantial change to existing environmental conditions or violation of any applicable federal, state, or local laws relating to the protection of the environment. It is the responsibility of the action proponent to evaluate all future specific actions resulting from this policy for compliance with the National Environmental Policy Act (NEPA), other applicable environmental requirements, and the U.S. Coast Guard Environmental Planning Policy, COMDTINST 5090.1 (series).

10. DISTRIBUTION. No paper distribution will be made of this Instruction. An electronic version will be located Coast Guard Directives System Library internally, and if applicable on the Internet at www.dcms.uscg.mil/directives .

11. RECORDS MANAGEMENT CONSIDERATIONS. Records created as a result of this Instruction, regardless of format or media, must be managed in accordance with the records retention schedules located on the Records Resource Center SharePoint Online site: https://uscg.sharepoint-mil.us/sites/cg61/CG611/SitePages/Home.aspx .

12. POLICY.

a. Pharmacy Operations.

(1) Responsibilities.

(a) The Regional Pharmacy Executive (RPE) will designate in writing a pharmacy trained Health Service (HS) technician as responsible for maintaining pharmacy procedures, including Health Insurance Portability and Accountability Act (HIPAA) and Reference (a) compliant privacy and security provisions.

(b) The RPE and pharmacy technician shall maintain pharmaceuticals according to applicable Federal laws, principally References (b) and (c), and observe the highest standards of professional practice and established pharmaceutical procedures to ensure best practices in patient safety and patient medication safety. Furthermore, when Federal laws conflict with State law, the RPE shall follow the more stringent pharmacy law.

(c) The RPE or designated pharmacy technician shall ensure adequate and appropriate current pharmacy references, hardbound, online access, or both.

(d) Through medical administration, the RPE or pharmacy technician will request funding to provide pharmacy services throughout the respective Area of Responsibility (AOR).

(e) RPE Mission Support Activities.

(1) The RPE shall provide assist visits at least annually to units they support and provide written reports of those assist visits to the RPM and the HSWL SC Pharmacy Consultant according to Ref (w)

(2) Pharmaceutical procurement and logistical support for clinics and operational units.

i. The RPE shall order medications and vaccines upon request by collateral units within 24 hours of receipt of a request; or if not available within 24 hours to align with the needs of the unit.

ii. Emergency orders shall be made available by the DLA Pharmacy Prime Vendor (Americsource Bergen Corp, or DMS Specialty Pharmaceuticals) ensuring delivery of pharmaceuticals within 6 hours if needed to support operational needs.

(3) Training.

i. RPE shall train and certify pharmacy technician watchstanders through "On the Job Training" (OJT) or with the Veterans Affairs virtual training program.

ii. RPE shall train clinic staff within their respective AOR on pharmacology and pharmacy therapeutics, at least quarterly.

iii. Pharmacy related training shall be completed with every assist visit.

(2) Authorized Prescribers.

(a) Practitioners authorized by federal and state law in their licensing jurisdiction to written prescriptions within the scope of their professional practice (e.g. physicians, dentists, nurse practitioners, physician assistants, optometrists) may prescribe pharmaceutical prescriptions in accordance with such authorization.

(b) While performing isolated duty or underway, per the afloat and ashore allowance lists, HSs may write and dispense pharmaceuticals under direction and advice from their assigned Designated Medical Officer Advisor (DMOA) within the scope of their professional practice.

(3) Prescriptions.

(a) Prescriptions written by CG providers. Prescriptions written by CG providers are honored at the facility where the prescription is written. In cases of emergencies, where it is advisable for a patient to start a prescription immediately and it is not available at the pharmacy, prescriptions may be written on form DD-1289 or other approved prescription blank(s) or submitted verbally or electronically so that the patient may have the prescription filled through the TRICARE pharmacy benefit. Prescriptions written by HSs will be filled only at the clinic where written.

(b) Non-clinic issued prescriptions. Prescriptions written offsite for formulary medications may be honored at CG pharmacy locations if verified by a pharmacist. If a pharmacist is not available, presented prescriptions will not be filled or dispensed. Prescriptions that are computer generated or electronically signed may be accepted at the RPE discretion.

(c) Telephone verbal and facsimile prescriptions. At the pharmacist's discretion, telephoned, verbal, electronic prescriptions and facsimile prescriptions may be accepted at pharmacist staffed locations only.

Pharmacists will not accept faxed prescriptions for DEA controlled substances/narcotics.

(d) Transferring prescriptions. Prescriptions may be transferred at the discretion of the pharmacist. Transfers will only be conducted between licensed pharmacists.

(e) The prescriber shall personalize prescriptions. . If more than one member of a family is prescribed the same drug, a separate prescription shall be generated for each member.

(f) Scope of practice. Prescribers shall only prescribe items that treat conditions within the normal scope of the prescriber's professional practice and ethics.

(g) Cosmetic conditions. IAW with prescribed DOD Pharmacy and Therapeutics Committee (PTC)/TRICARE formulary guidance, (10 USC 1074(g) and 32 CFR 199.21) CG clinic shall not honor or stock prescriptions for medications that only treat cosmetic conditions (baldness, wrinkles, etc.). Additionally, vitamins and supplements not covered by TRICARE will not be stocked or prescriptions honored.

(h) Prescriptions for animals. CG pharmacies will not fill prescriptions for animals unless the animal is government owned.

(i) Special order medications. Special order medications written by an authorized CG provider may be ordered at a CG clinic for dispensing with approval from the respective Regional Practice PTC.

(j) Self-prescribing. Prescribers will not prescribe controlled medications for themselves or their family members except as provided herein. If controlled medication is required and no other authorized prescriber is assigned to the clinic or sickbay, the CO, or Executive Officer (XO), shall review, approve, and countersign each controlled prescription. Only after such CO or XO review, approval, and countersignature, may pharmacy personnel fill the medication.

(4) Formulary medications. CG pharmacies shall honor prescriptions from authorized providers for eligible beneficiaries for products on the clinic's formulary provided a pharmacist is available on site.

(a) Clinic formularies are based on the DoD PTC formulary guidance and any additional CG formularies such as the Health Service Allowance List afloat and ashore.

(b) All CG clinics with a pharmacy shall maintain a formulary of adequate stock to provide support of normal daily operations. Formulary inventory may be minimally stocked, however medication shall be made available within one business day.

(c) Medications resulting from referral visits shall not be filled locally unless the prescription is a formulary medication. Patients will follow-up with referring CG provider for suitable formulary alternatives.

(d) Each CG regional practice will participate in the national CG PTC and follow guidance developed by the CG PTC to include at a minimum a current formulary available upon request.

(5) Prescribing.

(a) The CG method of medication prescribing is defined IAW Reference (a).

(b) Pharmacists and pharmacy technicians have full access to the provider notes, labs, etc. for the purpose of filling a prescription with their normal scope of practice.

(c) Prescribers and pharmacy personnel will avoid the use of abbreviated names of medications and unapproved acronyms to prevent medication errors and enhance patient safety per Institute for Safe Medication Practices (ISMP) and accreditation guidelines.

(d) The standard quantity issued for chronic conditions is a 90-day supply or per DoD PTC guidelines on quantity limitations per the TRICARE pharmacy benefit. Due to operational commitments, Active Duty (AD) members may dispense larger quantities (up to 180 days). AD members deploying Outside the Continental United States (OCONUS) for greater than 180 days shall use the TRICARE Deployed Prescription Program.

(e) Pharmacy staff utilizing an Electronic Health Record (EHR) are not required to keep a prescription log. However, the pharmacy staff that prepared and checked the prescription shall initial the label in ink.

(f) Pharmacy staff not utilizing an EHR will maintain a drug-dispensing log, containing prescription number, patient's name, patient's social security number and/or DoD identification number, drug name, drug manufacturer, lot number and the medication’s expiration date. This log will be properly secured in accordance with HIPAA and Privacy law and policy, and retained for three years.

(g) Pharmacy staff will maintain prescriptions for a minimum of five years or IAW state regulations, whichever is longer.

(h) At clinics where prescription dispensing occurs, medications will be double- checked if not prepared by a pharmacist prior to dispensing to the patient pursuant to the following:

(1) When the pharmacist is absent, the pharmacy technician will employ a mandatory second check of all prescriptions which will be performed by

a pharmacist remotely, and if a pharmacist is unavailable, a medical or dental officer within the clinic.

(2) At clinics where neither a pharmacist nor a "C" school pharmacy trained technician is available. Corpsmen that have completed the pharmacy technician qualification, as delineated by HSWLSCTD 2018-04 (ref x), may on a temporary basis, but for not more than 6 months, prepare and dispense prescriptions that have been double checked (with appropriate medical officer (MO) document) by the MO at the local clinic.

(6) Dispensing.

(a) Prescription verification. Except for approved non-prescription program items, pharmacy staff shall only dispense stocked items upon receiving a valid prescription. If the pharmacy staff receives an illegible prescription or questions a prescription's authenticity, dosage, compatibility, or directions to the patient, the pharmacy staff must obtain clarification from the prescriber before the dispensing the medication(s).

(b) Patient identification. When dispensing medication(s) to patient(s), the dispenser shall identify the patient through a military identification card. In the event the patient cannot present to pick-up their medication(s), the patient may designate an authorized patient representative with proper notification/consent pursuant to HIPAA provisions (e.g. a copy of the patient's identification card front and back with a signature from the patient or an email sent from the service member's official email).

(c) Medication Reconciliation. Pharmacists shall, to the best of their ability, complete a medication reconciliation to include all active medications, over-the-counter medications, and dietary supplements before dispensing new medications.

(d) Medication containers. Pharmacy staff will use Child-resistant containers to dispense all prescription medications except for legally non-childproof required pharmacy products (e.g. sublingual nitroglycerin tablets), which are to be dispensed in the original packaging. The prescribing provider or the patient may specifically request a conventional (non-child resistant) closure in place of the childproof container. The prescription order shall be documented in the EHR for non-childproof container requests generated by the provider.

(e) Medication information. Pharmacy staff shall, to the best of their ability, provide patients with a printed copy of the medication(s) patient education monograph with all new dispensed prescriptions. Additionally, Pharmacy staff shall provide FDA required Medication Guides.

(f) Medication Error. In the event of a medication error or near miss, the person responsible for the error will complete a Patient Event Reporting Template (PERT) form. The clinic administrator will submit a copy of the PERT for review during the next convening Quality Improvement Focus Group (QIFG) meeting.

(g) Adverse medication reaction reporting.

(1) Clinics shall submit patient adverse reactions or product quality problems via the Food and Drug Administration (FDA) MEDWATCH system on FDA Form 3500, which can be obtained from the FDA at 1-800-FDA-1088 or at the FDA website: www.fda.gov.

(2) Clinics shall submit adverse reactions to vaccines using the Vaccine Adverse Event Reporting System (VAERS). VAERS forms can be obtained from the FDA website. www.fda.gov.

(h) Refills. CG Pharmacy staff may refill prescriptions (except for controlled substances) when authorized by the prescriber. Pharmacy staff will not refill prescriptions after one year from the date it was written. Prescriptions shall not be refilled from the container label. Refills shall be verified in the pharmacy prescription system before a refill is dispensed to the patient.

(i) Non-prescription Medication Program (OTC). CG clinics are encouraged to establish non-prescription medication programs. CG units not staffed with an HS may only operate a non-prescription medication program with oversight provided by a RPE or supporting independent duty health service technician (IDHS) per HSWL SC guidance.

(j) Night Locker. Clinics that are authorized to dispense medications may utilize a night locker. A night locker contains a minimal number of prepackaged medications, locked, monitored, and only utilized after normal duty hours. Persons dispensing medication from the night locker shall document the activity in the pharmacy electronic patient profile.

(k) Pharmacy staff will not fill prescriptions generated from sources outside of the CG clinic after regular pharmacy operating hours. In these situations, patients will be advised of alternative pharmacy points of services resource availability.

(l) Drug samples are not authorized at any CG facility.

(m) Pharmacy Staff will post a sign outside of the pharmacy practice site in a highly visible location stating, “Please inform our pharmacy staff if you are breast feeding or may be pregnant.”

(7) Drug Dispensing Without a MO.

(a) General. Independent Duty Health Service Technicians (IDHS) conducting

dispensing operations without a Medical Officer (MO) shall be conducted IAW provisions of this Instruction and the Health Services Allowance List. These services are available to active-duty personnel only. IDHSs in these situations are encouraged to seek consultation with their RPE.

(b) Child-Resistant Containers. Pharmacy Staff dispensing prepackaged over-the-counter (OTC) products shall issue products in their original container. For vessels, limited quantities of prescription drugs may be issued in labeled plastic zip-lock bags and retained by the patient while underway with proper labeling including name of patient, name of medication, exact instructions, precautions, and warnings regarding the medication, date dispensed, and initials of dispenser. However, personnel shall issue these bags inserted in a child resistant container with proper labeling when removed from the vessel.

(c) COs afloat may authorize temporary deviations from the controls established in this chapter due to operational or emergency situations.

(d) Formulary. IDHSs shall maintain drug formularies consisting of:

(1) Standardized Health Services Drug Formulary items.

(2) Health Services Allowance List Afloat requirements.

(3) Chronic medications prescribed by a physician for active-duty members currently assigned to the duty station.

(4) Other drugs the HS has been authorized in writing by the DMOA to stock for their active-duty members. A copy of the DMOA's written approval of these medications will be forwarded to the RPE for review, approval and acquisition. The review will ensure compliance with the DoD PTC based formulary.

(8) Labeling. Pharmacy personnel will prepare and securely affix a label for each prescription dispensed. The label will include appropriate auxiliary labelling and must show at a minimum:

(a) Facility identity, including the pharmacy address and telephone number.

(b) Unique identifying prescription number.

(c) Prescriber's name.

(d) Concise patient instructions.

(e) Generic drug name and strength.

(f) Quantity dispensed.

(g) Patient's first and last name.

(h) Method of identifying individual(s) who prepared the prescription label and/or the individual who double-checked the prepared prescription.

(i) The legend "KEEP OUT OF THE REACH OF CHILDREN" on all prescription labels.

(j) Date prescription filled.

(k) Refill status.

(l) Expiration date for prepared and compounded prescriptions (e.g., liquid antibiotics, dermatologic products, etc.).

(m) The legend "CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED" (for controlled substances only).

(n) Necessary supplemental or auxiliary labels.

(o) Medicinal compounded preparations packaged in the pharmacy for subsequent issue shall be identified and labeled with the full generic name. The manufacturer's name, lot number, and expiration date, if any, must be shown on the label.

(9) Drug Stock.

(a) Source of medications. The Defense Logistics Agency (DLA) is the primary source of pharmaceuticals from the DLA negotiated Pharmaceutical Prime Vendor Program and contracts. Other Federal sources may be used when medication is unavailable, or the price/service advantages are determined to be the most cost-effective procurement method for the clinics.

(b) Nutritional/Herbal/Dietary Supplements/Medications and Performance Enhancing Substances. CG pharmacies shall not stock these products. The Human Performance Resource Center (HPRC) Operations Supplement Safety (OPSS) is the recognized consultative resource authority for matters involving these matters. Comprehensive guidance is available at https://www.opss.org/. Aviators, flight crewmembers, and divers will follow applicable guidance for supplement use.

(c) Separation of dosage forms. Pharmacy staff will physically separate by route of administration (e.g. topical, oral, injectable, otic, inhalant, ophthalmic, etc.) and by physical property (e.g. tablets vice liquids) all medications stocked. These provisions decrease the likelihood of inadvertent selection errors and enhance patient safety.

(d) United States Pharmacopeia (USP) 800 – Hazardous Medications. Pharmacy Staff shall separate all hazardous medications as defined by USP 800 from the stock of non-hazardous medications. All Individuals receiving, handling, and dispensing hazardous medications will use proper personal protective equipment (PPE) IAW USP 800 regulations.

(e) Multiple Dose Injectable. All individuals who open multiple dose injectable vials will date the vial upon opening. The expiration date must be reflected as twenty-eight (28) days from the opening of the product, except in situations where the manufacturer's product information indicates a shorter expiration date. MultiDose vaccine vials will expire with the manufacturer's expiration date, unless otherwise noted by manufacturer.

(f) Refrigerated items. Pharmacy staff will store pharmaceuticals requiring refrigeration within proper refrigeration equipment (e.g. refrigerator, or transport unit) which meets the USP criteria for pharmaceutical storage. Refrigerators must have alarms, constant temperature monitoring, and recording devices that will be connected to an emergency power supply to protect refrigerated medications in the event of an electrical malfunction or power surge. Pharmacy staff will check temperature readings and record readings twice daily Temperatures which register outside the acceptable storage range will be immediately reported to the RPE and the health service administrator (HSA) (if ashore) or the XO (if afloat). Refrigerated medications must be stored and maintained at a temperature between 36-46 degrees Fahrenheit. The HSWL SC pharmacy technical authority may be contacted for further guidance on resources for obtaining refrigerators and temperature monitoring devices. Pharmaceuticals will not be stored in the same refrigerator used to store food as the potential increased access to the food refrigerator compromises the stable temperature environment. Additionally, the potential hazard of vaccines contaminated by food spill or spoilage could compromise the vaccine.

(g) Room Temperature Items. Pharmacy Staff will store medications that are identified as requiring storage at room temperature within a USP temperature range of 68-77 degrees Fahrenheit.

(h) Flammable. Pharmacy staff will store flammable compounds according to accepted fire safety regulations. Additional information regarding these items can be found through local or regional HAZMAT coordinator.

(i) Pharmaceutical Hazardous Waste (PHW) management IAW Reference (i).

(1) All CG pharmacies, clinics, and IDHS sick bays that generate PHW, shall designate a PHW accumulation area and label accordingly.

(2) HSWL SC shall designate a PHW handler at every PHW generating site. The PHW handler will ensure compliance with local, state and federal

regulations and shall:

i. Complete annual training with the local hazardous waste program manager.

ii. Make the waste determination.

iii. Store and transfer all PHW to the unit hazardous waste vendor at least on an annual basis.

iv. Designate a section of the clinic or sickbay as a PHW collection site.

v. Ensure proper container labeling.

(j) Shelf-Life Extension Program (SLEP). Pharmacy staff shall enter all Medical Counter Measure (MCM) inventory into the DOD FDA SLEP database. If the clinic MCM is identified to be tested, pharmacy staff shall label it with the project number and forward a sample to the FDA SLEP coordinator. The FDA SLEP coordinator shall provide the disposition of extensions to submitted products.

(k) Poison control telephone reference. Pharmacy staff shall post the national poison control numbers in the pharmacy and other pertinent clinic areas. The National Poison Center telephone number is (1-800-222-1222).

(l) Credit return program (Reverse Distribution Program). Clinic pharmacies and sickbays will abide by DLA established credit return program provisions. The cognizant RPE shall actively manage and provide oversight of these assets for their regional practice. The reverse distributor representative will present pharmacy personnel with a printed inventory of all returned pharmaceuticals. Before the pharmaceuticals are removed from the practice site. If controlled substances are included in the pharmaceutical returns, pharmacy personnel will complete, sign and retain proper documentation (e.g., DD-1149, Requisition and Invoice/Shipping Document and NAVMED 6710, Perpetual Inventory).

(10) Pharmacy Security.

(a) CG pharmacies are restricted areas. Access to CG pharmacies is limited and maintained IAW Reference (j).

(b) Doors. Solid core doors with one-inch (minimum), dead bolt locks shall be used for all pharmacy and medical supply areas. Pharmacy staff shall ensure the pharmacy is secured at the end of the day. On Dutch doors, both sections must have this type of lock. Pharmacy doors must always remain secured with a second key lock or cipher lock.

(c) The pharmacy must have a personnel identification and controlled system, including an entry/departure log, and an access list posted inside the pharmacy.

(11) Pharmacy Therapeutics Committee (PTC).

(a) PTC is a mandatory advisory committee that will meet centrally with participation by all CG clinics on a quarterly basis in a face-to-face, video, or teleconference. HSWL SC Chief of Operational Medicine shall serve as Chair of this committee, and the HSWL SC Pharmacy Consultant shall serve as the Secretary.

(b) Recommendations made by the PTC are subject to the approval of the PTC chair. The basic processes of this committee are delineated by the HSWL SC.

(12) White Space Reports

(a) RPEs shall request white space reports through DHA Pharmaceutical Operations and Support Center on at least a quarterly basis.

(b) RPEs shall review the report for their given AOR and coordinate all findings with the regional practice team. Document findings in quarterly CG PTC meetings.

b. Controlled Substances.

(1) General.

(a) Controlled substances, as used here, are defined as.

(1) Drugs or chemicals in Drug Enforcement Agency (DEA) Schedules I-V: (for example, the manufacturers label for Acetaminophen with Codeine #3(30 mg.) carries the DEA symbol for Schedule III (C-III) and will be treated as a Schedule III by CG units.). NOTE: The use of Schedule I, II, III, IV, and V is synonymous to C-I, C-II, C-III, C-IV, and C-V, respectively.

i. Precious metals.

ii. Ethyl alcohol (excluding denatured).

iii. Other drugs or materials the local CO or national PTC determine to have significant abuse potential.

(2) CG authorized uses for controlled substances are limited to the following.

i. Medicinal purposes when accompanied by a valid prescription

ii. Other uses CG Regulations specifically authorize.

(3) The following controlled substances are not authorized, even if they meet the requirements of section b.1.a.2 above.

i. Amphetamines for fatigue management or performance enhancement (go- pills).

ii. Ephedra derivatives, including ephedrine.

iii. Schedule I or C-I drugs.

(2) Custody and Controlled Substance Audits.

(a) Controlled Substance Custodian (CSC).

(1) Pharmacy Officers, where billeted, will be appointed in writing as the CSC by the Regional Practice Manager (RPM).

(2) In the absence of a Pharmacy Officer, the RPM will designate the HSA as the CSC.

(3) Medical and Dental Officers may not serve as alternate CSCs, which avoids a possible conflict of interest.

(4) Temporarily assigned personnel may not serve as CSCs or alternates.

(5) IAW Reference (v) Chapter 6-2-3-A-(6), the XO is directly responsible for medical matters if a MO is not assigned. For sickbays, the CO will designate a commissioned officer as the CSC.

(6) The Controlled Substance Audit Board (CSAB) shall conduct an inventory audit of all controlled substances whenever the CSC is changed. The CSAB shall document the audit by memorandum, sign, forwarded to the RPM, and retain in the pharmacy controlled substance audit record.. The outgoing CSC will transfer all keys and the local command security officer shall change all combination locks.

i. Controlled Substance Audit Boards (CSAB). Each clinic pharmacy procuring, storing, or dispensing controlled substances will have a CSAB conducted monthly for shore pharmacies and quarterly for afloat sickbays.

ii. DEA Biennial Inventories. To comply with DEA requirements, the CSC

shall inventory all controlled substances during May of Even-Numbered years. The CSC shall maintain a copy of the CSAB report for Narcotics and Other Controlled Drugs, CG-5353 on file locally in the pharmacy and labeled "FOR DEA BIENNIAL INVENTORY" at the top of the form.

iii. HSWL SC shall delineate the CSAB processes in a technical directive.

(3) DEA Registration.

(a) DEA registration is required for those CG clinic pharmacies with Prime Vendor (PV) ordering capability. Purchase of controlled substances from commercial sources is prohibited unless approved and procured by the RPE of the practice site. The RPE shall forward the clinic's DEA renewal to the HSWL SC Pharmacy Consultant as the approving authority for "fee exempt" status for processing of the clinic's DEA certificates.

(b) The HSWL SC Pharmacy Consultant shall complete DEA renewals online.

(4) Reporting Theft or Loss. Theft or loss of controlled substance is defined as any discrepancy for which all accountability processes (e.g. internal audit, CSAB, or investigation) have been exhausted with negative results. NOTE: Overage or shortage of one (1) to two (2) tablets/capsules from a newly opened bottle of controlled substance does not constitute theft or loss but will be notated in the Perpetual Inventory as manufacturer's bottling discrepancy. Any member that identifies ANY discrepancy will immediately, upon discovery (within 24 hours) notify the HSWL SC Pharmacy Consultant for guidance.

(5) Procuring, Storing, Transferring, and Disposing of Controlled Substances.

(a) Procurement.

(1) Clinic pharmacies shall procure controlled substances from the DLA prime vendor source. CG vessels shall obtain authorized controlled substances through their respective RPE.

(2) Schedule I controlled substances and alcoholic beverages are prohibited and will not be procured or stocked in CG health care facilities.

(3) Upon receipt, controlled substances will immediately be placed in the custody of the CSC.

(b) Storage.

(1) Controlled substances shall be stored in an all-purpose GSA Class V safe and in accordance with Reference (j), which offers in-depth guidance regarding storage of Controlled Substances.

(2) If mission needs necessitate acquisition and storage that exceeds the storage capacity of the Class V safe, then Pharmacy staff may store controlled substances in a secured locked cabinet in a controlled access and temperature-controlled area in coordination with the HSWL Regional Practice Manager. The RPE shall coordinate the procurement of an appropriate GSA class V safe with the HSWL-SC Pharmacy Consultant in a timely manner. See HSWL SC for further direction.

(3) Afloat units may use existing physical and integral containers that are built into the ship structure to store controlled substances. Such containers shall be secured at all times with positive control.

(c) Transfer.

(1) Controlled substances will be transferred between CG and other government facilities using the Requisition and Invoice/Shipping Document, Form DD-1149. Before a transfer can be made, the form must include the following;

i. Names of issuing and receiving facility or unit.

ii. Name, strength, lot and manufacturer and quantity of each drug.

iii. Dates. The preparer shall annotate the date that form was prepared. The receiving unit shall annotate the date that the physical transfer occurred.

iv. Signatures of the issuing and receiving custodians.

v. Both units will adjust inventories as required and file copies of the Requisition and Invoice/Shipping Document, Form DD-1149 for five years. A copy of the requisition and invoice/shipping document, DD-1149 will be sent back to the originating site.

(d) Disposal.

(1) The CSC will properly label expired, contaminated, damaged, or otherwise unusable controlled substances and isolate in the controlled substance safe from usable and in-date items. The CSC will ensure that the unserviceable controlled substances are included in the next shipment of pharmaceutical returns goods for credit or destruction.

(2) Pharmacy personnel will acquire a signed and dated inventory summary from the pharmaceutical reverse distributor prior to the transfer of returned controlled substances and maintained for three (3) years.

(6) Prescribing Practices.

(a) Authorized prescribers are exempt from registration under provision of 21 CFR 1301.23(a). In lieu of a DEA registration number, an authorized provider may use their National Provider Identification (NPI) registration number along with the clinic DEA number when prescribing medications dispensed at the clinic pharmacy IAW Reference (t). Each individual will use a specific internal code number as a suffix to the institution's DEA registration number. The standard practice for the suffix is to use the provider's NPI number with the facility DEA when submitting the prescription [facility DEA]-[provider NPI] (ex. AB1234567-9876543219). The suffix must be unique to the prescriber and clearly indicated, when possible notate the prescription. A current list of internal codes/suffix assignments (NPI) and corresponding individual providers must be maintained by the institution and should be made available upon request to verify the authority of the prescribing individual.

(b) Where an authorized provider prescribes outside of their official duties, the prescriber is required to register with the DEA, at his or her own expense, and comply with applicable state and federal laws.

(7) Signatures.

(a) An authorized prescriber will sign all prescriptions for controlled substances. For medical provider prescriptions generated and signed via Electronic Health Record (EHR), the pharmacy staff shall generate a duplicate pharmacy label of the ordered controlled substance, placing it on a prescription blank and the patient will sign and date the back of the prescription when dispensed.

(b) The back of all controlled substance prescriptions will include the wording "RECEIVED BY:" followed by the patient's signature, address, the date dispensed, and quantity received by the patient. The patient will observe the amount dispensed during the course of the second (dual integrity) count or at time of dispensing.

(8) Quantities and Refills.

(a) Controlled substances shall be prescribed in minimal quantities consistent with proper treatment of the patient's condition. Pharmacists may honor controlled substance prescriptions generated from a source other than the CG clinic for formulary items at the practice site where a pharmacist is available.

(b) Pharmacists may, in their professional judgement dispense out of state controlled substance prescriptions if the prescription appears legitimate.

(c) Schedule II prescriptions will not be accepted more than seven days after the date the prescription was written. For Schedule III through V, prescriptions will not be accepted more than six months after the date the prescription was written.

(d) Schedule II prescriptions will be limited to a maximum of 30-day supply.

The only exception will be medication for attention deficit disorder (ADD) where quantities may be dispensed in up to a 90-day supply. Refills are not permitted on Schedule II drugs.

(e) Schedule III, IV, and V prescriptions will be limited to 30-day quantities with up to five refills within a 180-day period and only when authorized by the prescriber. The only exception will be for chronic seizure medications, which may be dispensed in up to 90-day quantities with one refill (six months' total supply). Prescriptions generated at sources outside of a CG clinic will only be honored for these quantities, at the discretion of the pharmacist. Patients will be informed of this quantity or refill limitation at the time of the initial prescription presentation, allowing the patient the opportunity to have the prescription(s) filled elsewhere.

(f) Controlled prescriptions will not be commonly filled until the patient, for whom it is intended, is available to pick up the medication. This should also include refills. However, if a pharmacy's workload is judged in the pharmacist's best interest to maintain pharmacy workflow, refill of controlled substances may be completed in advance as long as the pharmacy personnel ensures positive and secured control until the patient picks up the medication. These refills will be bagged and/or sealed in such a way to ensure tamper resistance. Additionally, they will be housed in a central location such that at the end of the day, those controlled prescriptions not picked up will be returned to the narcotics safe for storage.

(9) Filing Prescriptions.

(a) Controlled substance prescriptions will be serially numbered and maintained in two files:

i. File #1: All C-II, precious metals, and alcohol prescriptions.

ii. File #2: All C-III, C-IV, and C-V prescriptions.

(b) All prescriptions will be maintained on file for three (3) years after which they may be destroyed by shredding.

(c) All controlled prescriptions will be documented on a perpetual inventory.

c. Pharmacy Forms and Records.

(1) General. Records shall be maintained for certain procedures conducted within all CG clinics. Among mandatory requirements for record keeping are the prescribing of medications, handling of controlled substances, and quality control procedures. Standardized forms are available for all procedures except quality control.

(2) Prescription Forms.

(a) Medical providers shall write prescriptions on the DoD Prescription blank, DD- 1289 or equivalent, or SF-600 for in-house dispensing when chart prescribing or EHR is not available.

(b) All prescriptions dispensed in CG pharmacies shall be filed separately as such:

(1) Non-controlled prescriptions

(2) Schedule II prescriptions

(3) Schedule III, IV, and V prescriptions

(c) Prescriptions shall be written in black or blue ink, indelible pencil, typed or printed, and will include the following:

(1) Patient's full name.

(2) Date the prescription was written.

(3) Full generic name (or trade name with substitution instructions), dosage form desired, and dosage size or strength written in the metric system. The quantity dispensed shall be clearly specified numerically (e.g.: "one bottle" or "one package" are not acceptable). When controlled prescriptions are written, the numeric quantity shall also be written out and in parentheses next to the numeric amount (e.g. Disp. 12 (twelve) tablets). Standard pharmacy abbreviations may be used in writing dispensing and dosage instructions but not in specifying the drug to be dispensed.

(d) Complete, explicit and distinct directions to the patient are required on all prescriptions. Expressions such as "take as directed," "label," etc. are NOT allowed.

(e) Prescriber's legible, legal signature (initials not permitted) with printed or stamped name and professional discipline (MD, DO, DMD, DDS, PA, HS, etc.). When EHR entry is utilized, electronic signature satisfies this requirement.

(f) All additional requirements when prescribing controlled substances:

(1) Patients complete address.

(2) Prescriber's SSN, DEA or NPI number.

(3) NOTE: Alterations on prescriptions for CII controlled substances are prohibited.

(g) Maintenance of all prescriptions on file, including all "prescription logs" related to chart prescribing is required for three (3) years, after which they may be destroyed by shredding. The pharmacy will have readily retrievable access to the patient's medical information, including provider's current patient visit entry, patient's current medications, age, allergies, weight, etc., when preparing and dispensing prescriptions.

(3) Quality Control Forms. For compounding and prepackaged items, locally prepared form shall be used, which provides material sources (to include manufacturer's name, lot numbers, and expiration dates), compounding procedures, new expiration date, intermediary and final checks by supervisory personnel, and labeling.

(4) Controlled Drug Forms.

(a) The following forms are available for use in maintaining controlled substance inventory:

(1) The serial number of new Narcotic and Controlled Drug Account Record, NAVMED 6710/1.

(2) The Narcotic and Controlled Drug Inventory-24 Hours, NAVMED 6710/4.

(3) Perpetual Inventory of narcotics, Alcohol, and Controlled Drugs, NAVMED 6710/5.

(b) The use of the controlled drug forms shall be delineated by the HSWL SC.

13. FORMS/REPORTS. The forms referenced in this Instruction are available on the Coast Guard Standard Workstation or on the Internet: www.dcms.uscg.mil/Our-Organization/Assistant- Commandant-for-C4IT-CG- 6/The-Office-of-Information-Management-CG- 61/Forms- Management/.

14. SECTION 508. This Instruction adheres to Accessibility Guidelines and Standards as promulgated by the U.S. Access Board. If changes are needed, please communicate with the Coast Guard Section 508 Program Management Office at: Section.508@uscg.mil.

15. REQUEST FOR CHANGES. Units and individuals may recommend changes via the chain of command to: HQS-DG-lst-CG-112@uscg.mil.

/DANA L. THOMAS/
Rear Admiral, U. S. Coast Guard
Director, Health, Safety, and Work-Life